REMARKS

This Amendment is responsive to the Office Action dated July 26, 2006. Applicant has amended claims 4-6, 9, 15, 18, 19, 21, 22 and 25 and cancelled claim 24. Claims 1-23 and 25-27 are pending.

Claim Objections

In the Office Action, the Examiner objected to claims 4-6, 15 and 19 for informalities. Applicant thanks the Examiner for notifying Applicant of these informalities. In this Amendment, Applicant has resolved each of the informalities pointed out by the Examiner.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 9-12 under 35 U.S.C. § 102(b) as being anticipated by Silverman et al. (US 5,358,197). The Examiner also rejected claims 13-15, 18-19 and 21 under 35 U.S.C. § 102(b) as being anticipated by Silvestrini (US 5,824,086). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provide no teaching that would have suggested the desirability of modification to include such features.

Claims 9-12

Silverman et al. (US 5,358,197) fails to teach or suggest wherein the bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, as recited by Applicant's claim 9 as amended.

For at least this reason, Silverman et al. (US 5,358,197) fails to disclose each and every limitation set forth in claims 9-12 as required to support a proper rejection under 35 U.S.C. § 102(b). Applicant respectfully requests the Examiner withdraw the rejection of claims 9-12 as being anticipated by Silverman et al. (US 5,358,197).

Claims 13-15

With respect to claim 13, Silvestrini (US 5,824,086) fails to disclose or suggest wherein the inner radius of the partial cylinder is sized to conform to close the anus of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the anus of the patient and when the patient exercises voluntary control over an external sphincter. For example, one example embodiment that includes such a feature is described at paragraph [0045] of Applicant's specification, "Inner surface radius 92 is sized to the dimensions of the anus of a particular patient, with a typical inner surface radius 92 being in the range of six to twenty-five millimeters."

In the rejection of claim 13, the Examiner failed to identify any teaching of this feature, and Applicant finds no such teaching in Silvestrini (US 5,824,086). The Examiner referred to FIG. 8A-8C. However, neither the cited figures, nor their accompanying description, has any dimensional information, much less suggests that the depicted insert has an inner radius sized to conform to close the anus of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the anus of the patient and when the patient exercises voluntary control over an external sphincter. In fact, Silverstrini is entirely focused on a corneal insert, and thus does not even suggest implantation proximate to the anus or anal sphincter. In the event the Examiner maintains the rejection of claim 13 under 35 U.S.C. § 102(b) as being anticipated by Silvestrini (US 5,824,086), Applicant respectfully requests the Examiner point out where Silvestrini (US 5,824,086) discloses bulking prosthesis in the shape of a partial cylinder having an inner radius sized to conform to close the anus of a patient.

Silvestrini (US 5,824,086) fails to disclose each and every limitation set forth in claims 13-15 as required to support a proper rejection under 35 U.S.C. § 102(b). Applicant respectfully requests the Examiner withdraw the rejection of claims 13-15 as being anticipated by in Silvestrini (US 5,824,086).

Claims 18-19 and 21

Silvestrini (US 5,824,086) fails to teach or suggest wherein the rod-like bulking prosthesis assumes an enlarged state in the presence of water, and wherein the rod-like bulking prosthesis has a length of at least ten millimeters when in the enlarged state, as recited by

Applicant's claim 18 as amended. Support for the amendment to claim 18 may be found from, e.g., paragraph [0042] of Applicant's specification.

For at least this reason, Silvestrini (US 5,824,086) fails to disclose each and every limitation set forth in claims 18, 19 and 21 as required to support a proper rejection under 35 U.S.C. § 102(b). Applicant respectfully requests the Examiner withdraw the rejection of claims 18, 19 and 21 as being anticipated by Silvestrini (US 5,824,086).

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 1-4 and 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Silverman (US 6,251,063) in view of Sawhney (US 2001/0046518). The Examiner also rejected claim 5 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Silverman (US 6,251,063) and Sawhney (US 2001/0046518) as applied to claims 1 and 4 and further in view of Silverman (US 6,385,197).

The Examiner rejected claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Silvestrini (US 5,824,086) in view of Capecchi et al. (US 5,489,300) and rejected claim 17 under 35 U.S.C. § 103(a) as being unpatentable over Silvestrini (US 5,824,086) in view of Van Bladel et al. (US 5,049,346). The Examiner also rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over Silvestrini (US 5,824,086) in view of Tu et al. (US 2002/0188308).

The Examiner rejected claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Johnson (US 6,098,629) in view of Hague et al. (US 2002/0072720). The Examiner also rejected claims 23 and 24 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Johnson et al. (US 6,098,629) and Hague et al. (US 2002/0072720) as applied to claim 22 and further in view of Boyd et al. (US 2001/0010021).

The Examiner rejected claims 25-27 under 35 U.S.C. § 103(a) as being unpatentable over Wilk (US 2002/0091295). Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 1-8

For example, with respect to independent claim 1, the applied references would not have made a method for treating fecal incontinence comprising implanting a bulking prosthesis in tissue proximate to an anal sphincter, wherein the bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation obvious to one of ordinary skill in the art at the time of Applicant's invention.

In the rejection of claim 1, the Examiner acknowledged that Silverman (US 6,251,063) fails to disclose wherein the bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, but stated that Sawhney (US 2001/0046518) would have made such a feature obvious to one of ordinary skill in the art at the time of Applicant's invention, In particular, the Examiner stated that it would have been obvious because, "the bulking prosthesis of Sawhney (US 2001/0046518) does not rely on precipitation of the implant from an injected solution...[i]f a mistake is made concerning the composition of a solution, the procedure may require adjustment, repair or replacement of the implant." The Examiner failed to provide support for the assertion that, if a mistake is made concerning the composition of a solution, the procedure may require adjustment, repair or replacement of the implant. Applicant does not find support for this statement anywhere in within Sawyney, or elsewhere within the prior art. As such, this statement appears to be no more than unsupported, hindsight speculation.

For its part, Silverman (US 6,251,063) emphasizes numerous advantages for precipitation of an implant from an injected solution. For example, Silverman (US 6,251,063) discloses at column 18, lines 37-42:

> Formation of implants which are too superficial in the wall 193 can interrupt the blood flow to the mucosa thereby causing the layer of the mucosa forming space 227 to eventually die and slough off. The injection of the augmenting material as a solution permits a relatively small needle. 61 to be utilized.

These advantages must be considered according to the legal standard for a prima facie case of obviousness as required to support a proper rejection under 35 U.S.C. § 103. The ultimate determination of patentability is based on the entire record, by a preponderance of

evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence.[1]

Thus, in order to substitute a bulking prosthesis in a miniature state at the time of implantation that assumes an enlarged state after implantation as recited in claim 1 for the disclosed injected solution implant of Silverman (US 6,251,063), the Examiner must find evidence that would have motivated one of skill in the art to modify Silverman (US 6,251,063) in light of these disclosed advantages of the injected solution implant. Applicant asserts that the Examiner has failed to cite any such support in the teachings of the prior art.

For at least these reasons, the current rejection fails to establish a prima facie case for non-patentability of Applicant's claims 1-8 under 35 U.S.C. § 103(a). Withdrawal of the rejections of claims 1-8 is requested.

Claims 16, 17 and 20

The additional references applied in the rejections to claims 16, 17 and 20 fail to overcome the deficiencies of the applied references in the rejections of independent claims 13 and 18. For example, Capecchi et al. (US 5,489,300) and Van Bladel et al. (US 5,049,346) fail to disclose or suggest an inner radius of the partial cylinder sized to conform to close the anus of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the anus of the patient and when the patient exercises voluntary control over an external sphincter as recited in independent claim 13. Indeed the Examiner has not relied on Capecchi et al. (US 5,489,300) or Van Bladel et al. (US 5,049,346) as disclosing such a feature, and Applicant finds no such feature in either Capecchi et al. (US 5,489,300) or Van Bladel et al. (US 5,049,346).

Likewise, Tu et al. (US 2002/0188308) fails to disclose or suggest wherein the rod-like bulking prosthesis assumes an enlarged state in the presence of water, and wherein the rod-like bulking prosthesis has a length of at least ten millimeters when in the enlarged state, as recited by Applicant's claim 18 as amended.

For at least these reasons, the current rejections fail to establish a prima facie case for non-patentability of Applicant's claims 16, 17 and 20 under 35 U.S.C. § 103(a). Withdrawal of the rejections of claims 16, 17 and 20 is requested.

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[1] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); see MPEP 2142.

Claims 22-23

Applicant amended claim 22 to recite the subject matter previously included in canceled claim 24. In the rejection of claim 24, the Examiner stated that Johnson (US 6,098,629) in view of Hague et al. (US 2002/0072720) disclose that surface textures, coatings structures may resist migration of the bulking prosthesis, but that Johnson (US 6,098,629) in view of Hague et al. (US 2002/0072720)does not specifically teach machining of a helical thread. Nonetheless, the Examiner stated that it would have been obvious to one of ordinary skill in the art at the time of the invention to manufacture a bulking prosthesis similar to that of the combination of Johnson et al. (US 6,098,629) and Hague et al. (US 2002/0072720) because a slot and or helical threading will facilitate ingrowth around the prosthesis, which secures the prosthesis within the implantation site and promotes sealing of the surrounding tissue as described by Boyd et al. (US 2001/0010021) at paragraph [0009], lines 14-18.

In this rejection, the Examiner has significantly mischaracterized the disclosure of Boyd et al. (US 2001/0010021) at paragraph [0009], lines 14-18. For reference, this paragraph is reproduced below:

> **[0009]** The present invention further contemplates a method of inserting a device formed in accordance with the present invention. Specifically, the method includes providing an insertion tube and an implant formed of bone having a first and second portions joined by a flexible central portion. The insertion tube is positioned adjacent a disc space formed by adjoining vertebrae. The first and second portions of the bone implant are then positioned into a reduced size configuration for insertion into the insertion tube. The implant is then inserted into the tube and advanced until it is positioned in the disc space. Once the implant is in the desired position, the first and second portions are moved with respect to one another by flexing of the flexible portion into an expanded implantation configuration. In a preferred embodiment of the insertion method, bone ingrowth material is placed between the first and second portions to encourage further bone ingrowth into and around the fusion devices.

This excerpt merely describes using bone ingrowth material to encourage further bone ingrowth. This excerpt does not even mention of use of a slot and or helical threading to facilitate ingrowth around the prosthesis, to securing the prosthesis within the implantation site, or to promoting sealing of the surrounding tissue.

Furthermore, the helical thread described in Boyd et al. (US 2001/0010021) is formed on a bone fusion material and used to engage bone.[2] Neither Johnson et al. (US 6,098,629), Hague et al. (US 2002/0072720) nor Boyd et al. (US 2001/0010021) provide any use for such a feature on a rod-like bulking prosthesis that comprises a hydrophilic polymer and has a sharpened tip. In this manner, Boyd et al. (US 2001/0010021) fails to describe any particular advantages or other teachings that would motivate one of skill in the art to deviate from the disclosures of Johnson et al. (US 6,098,629) and Hague et al. (US 2002/0072720) in a manner that would result in Applicant's claimed invention.

For at least these reasons, the current rejection fails to establish a prima facie case for non-patentability of Applicant's claims 22 and 23 under 35 U.S.C. § 103(a). Withdrawal of the rejections of claims 22 and 23 is requested.

Claims 25-27

Wilk (US 2002/0091295) fails to teach or suggest implanting a rod-like bulking prosthesis having a sharpened tip proximate to an anal sphincter, wherein the bulking prosthesis assumes an enlarged state after implantation as recited by Applicant's claim 25 as amended. For at least this reason, the subject matter of claim 25 would not have been obvious to one of ordinary skill in the art at the time of the invention.

For at least these reasons, the current rejection fails to establish a prima facie case for non-patentability of Applicant's claims 25-27 under 35 U.S.C. § 103(a). Withdrawal of the rejections of claims 25-27 is requested.

[2] Boyd et al. (US 2001/0010021), paragraphs [0030]-[0031].

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserve the right to further address such rejections and/or characterizations.

No fees are believed to be due at this time. Please charge any additional fees or credit any overpayments to deposit account number 50-1778.

The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: DECEMBER 22, 2006

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